Translation is attached.

## RECEIVED Gentral fax center

Ø 003/014

JUN 2 5 2004

PTO/SB/08A (08-03)
Approved for use through 07/31/2006, OMB 0851-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
apond to a collection of information unless it contains a valid OMB control number.

Under the Paperwork Reduction Act of 199 Complete if Known Substitute for form 1449/PTO Application Number 09/899,026 Filing Date July 6, 2001 INFORMATION DISCLOSURE First Named Inventor Stamm STATEMENT BY APPLICANT Art Unit 1615 **Examiner Name** Sheikh Sheet 1 of 1 Attorney Docket Number 107664.115 US3

Document Number   Publication Date   Name of Patenties or Applicant of Cited Document   Pages, Columns, Lines, V Relevant Passages or Resemble of Relevant Passages or Resemble or Relevant Passages or Relev					DOCUMENTS	
US- 4,721,709	Examiner C Initials* N	1	Number-Kind Code <sup>2 (F Mount)</sup>	Publication Date MM-DD-YYYY		Pages, Columna, Lines, Where Relevant Passages of Relevant Figures Appear
US-	<i>X</i> \&	1	<sup>US-</sup> 4,721,709	01-26-1988	Seth et al	
US-	7					
US-						
US-			UŚ-			
US-			US-			
US-			us-			
US-			US-			
US-   US-			US-			
US- US- US- US- US- US- US- US- US- US-			US-			
US- US- US- US- US- US- US- US- US-			US-			
US- US- US- US- US- US-			US-			
US- US- US- US- US-			US-			
US- US- US- US-			U\$•			
US- US- US-			us-			
US- US-			US-			
US-			US-			
			US-			
US-			US-			
		7	US-			
FOREIGN PATENT DOCUMENTS				COREIGNEATE	NT DOCUMENTS	

	FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No.	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pagea, Columns, Lines, Where Relevant Passages	Γ		
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	MM-DD-YYYY		Or Relevant Figures Appear			
			<del> </del> -			-		
						Ę.		
	ļ.,					┝		

Examiner Sunce A- Sheekh	Osta Considered	8/18/0	
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Dra	w line through	citation (f not in	conformance and no
considered, include copy of this form with next communication to applicant. Applicant's unique citation of	esignation numb	ber (optional).	See Kinds Codes of
USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 2 Enter Office that issued the document.	by the two-lett	er code (WIPO	Standard ST.3), 1 Fo
Japanese patent documents, the Indication of the year of the reign of the Emperor must precede the serial management of t			
the appropriate symbols as Indicated on the document under WIPO Standard ST.16 if possible. Applicar			

Trainstation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application from to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Petent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETEO FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450,

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

PTO/SB/08A (08-03) Approved for use through 07/31/2008. OMS 0651-0031

	U.S. Petent and Trademark Office; U.S. DEPARTMENT OF COMMERC
Under the Paperwork Reduction Act of 1995, no persons are required to n	espond to a collection of information unless it contains a valid OMB control number
Supstitute for form 14A9/PTCX	Complete if Kriown
	Application Number 09/899,026
INFORMATION DISCLOSURE	Filing Date:
	First Named Inventor Stamm
STATEMENT BY APPLICANT	Add Unit
(Use as many sheets 89 necessary)	, Examiner Name Sheikh
Sheet	-Attorney: Docket Number 107664.1.15 US3

Examiner	Cite	Document Number	Publication Date	DOCUMENTS  Name of Patentee or	Pages, Columns, Lines, Where
lnitiale*	No.1		MM-DD-YYYY	Applicant of Cited Document	Relevent Passages or Relevant
. —		Number-Kind Code <sup>3</sup> (************************************			Figures Appear
		<sup>US-</sup> 2004/0092597	05-13-2004	Stamm et al	
		<sup>US-</sup> 2004/0058005	03-25-2004	Stamm et al	
		US- 2004/0058004	03-25-2004	Stamm et al	
		<sup>US-</sup> 2004/0057999	03-25-2004	Stamm et al	all
		<sup>US-</sup> 2004/0057998	03-25-2004	Stamm et al Stamm et al Stamm et al PRUP	
		<sup>US-</sup> 2004/0067997	03-25-2004	Stamm et al	
		US- 2003/0104060	06-05-2003	Stamm et al	
		ÜS- 2003/0104051	06-05-2003	Stamm et al	
		US-2002/0168413	11-14-2002	Stamm et al	
		US- 2002/0114839	08-22-2002	Stamm et al	
	<u> </u>	<sup>U\$</sup> 2002/0009496	01-24-2002	Stamm et al	
		US-			
		US-			
	l	US-			
•	_	US-			
		U <b>\$</b> -			
		US-			
		US-			
		US-			<u> </u>

examiner	Cite No.	Foreign Patent Document	IGN PATENT DOCU Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines,
Initials*	NO.	Country Code <sup>3</sup> "Number <sup>4</sup> "Kind Code <sup>5</sup> (if known)	MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages Or Relevant Figures Appear

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation front in conformance and not considered, include copy of this form with next communication to applicant. 'Applicant's unique citation designation number (optional). \*See Kinds Codes of USPTO Patent Documents at <a href="https://www.usplo.gov">www.usplo.gov</a> or MPEP 901.04. \*Enter Ordice that issued the document, by the two-letter code (WIPO Standard ST.3). \*For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. \*Kind of document by the sypropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. \*Applicant is to place a check mark here if English language Translation is attached.

Translation is attached.

This collection of Information is required by 37 CFR 1.97 and 1.98. The information is required to cottain or relain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentially is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patant and Trademark Office, P.O. 80x 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. 80x 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-788-9199) and select option 2.

PTO/SB/08B (08-03)

Approved for use birough 07/31/2006, OMB 0851-0031

U.S. Palent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1895, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for	form 11:449	MPTO		Complete if Known	
			Application Number	09/899,026	:::::::::::::::::::::::::::::::::::::::
INFOR	MAT	ION DISCLOSURE	Filing Date	July 6, 2001	:: :
STATE	MEN	IT BY APPLICANT	First Named Inventor:	Starnm	
			Art Unit	1615	' '
	750 85 Ma	ny sheets as necessary)	Examiner Name	Sheikh	. ; ; ; ; ;
Sticet 2	i in Gel.	of 2	Attorney Docket Number	107664.115 US3	
<u> </u>					
			ENT LITERATURE DOC		
Examiner Initials*	Cite No. <sup>1</sup>	the item (book, magazine, jou		of the article (when appropriate), title of talog, etc.), date, page(s), volume-issue try where published.	T <sup>2</sup>
$\bigcirc \emptyset$				of Delaware, Civil Action No.	
Jp		04-350, Reliant Pharma	aceuticals v. Abbott La	aboratories et al (1 June 2004).	
· V					
				,	
			***************************************	· ·	

	,		_	
Examiner Signature	afuneia N.S	hukh	Date Considered	8/18/04

\*EXAMINER: Initial if eference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (options!). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. This will wany depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sant to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DD NOT SEND FEES OR COMPLETED FORMS TO THIS ADORESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Substitute for form 1449/PTO	Со	mplete if Known	
K	Application Number	09/899,026	
MAR 3 0 2004 MINFORMATION DISCLOSURE	Filing Date	July 6, 2001	
	First Named Inventor	Stamm	
STATEMENT BY APPLICANT	Art Unit	1615	
(Use as many sheets as necessary)	Examiner Name	Sheikh	
Sheet 1 of 2	Attorney Docket Number	107664.115US3	

			U. S. PATENT D	OCUMENTS	
Examiner Initials*	Cite No.1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	L	Number-Kind Code <sup>2 (f known)</sup>			rigules Appeal
		US-	1		
		US-			
		US-			
	1	US-			
	<del> </del>	US-			
		US-			
	<del>                                     </del>	US-			•
		US-			
		US-		,	
	1	US-			
	1	US-	<u> </u>		
		US-	<u> </u>		
	<u> </u>	US-			
	<u> </u>	US-	<u> </u>	(k. // + // (k. // - // - // - // - // - // - // - //	
	·	US-			
	<b> </b>	US-			
		US-			
	<del>                                     </del>	US-			
		US-			

		FORE	IGN PATENT DOCU	IMENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
muais	NO.	Country Code <sup>3</sup> "Number <sup>4</sup> "Kind Code <sup>5</sup> (if known)	MM-DD-YYYY	Applicant of Cited Document	Or Relevant Figures Appear	T <sup>6</sup>
		EP 0 952 829 B1	03-05-2003	Stamm et al	ARI	
		EP 0 761 208 A1	03-12-1997	Duclos et al	- 10 PRIOR	
		WO 98/31361	07-23-1998	Stamm et al	NO	
Q/S		WO 96/01621	01-25-1996	Stubberud et al		
718		WO 82/01649	05-27-1982	Laruelle		
7						

Examiner Signature	Aumera	7. Skeekh	Date Considered	8/18/04
	<b>4</b>	1 . 0 /		1 ' / /

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. Senter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. Applicant is to place a check mark here if English language Translation is attached.

Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08B (08-03)

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Complete if Known Substitute for form 1449/PTO **Application Number** 09/899,026 INFORMATION DISCLOSURE Filing Date July 6, 2001 ATEMENT BY APPLICANT First Named Inventor Stamm **Art Unit** 1615 (Use as many sheets as necessary) **Examiner Name** Sheikh Attorney Docket Number of 2 107664.115US3

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Opposition to EP 0 952 829 (December 11, 2003) (English language translation).	V
		Opposition to EP 0 952 829 (December 11, 2003) (original French language document).	
gks		Handbook of Pharmaceutical Excipients, Second Edition, pages 392-399 (1994).	_
			-

Examiner Signature Quince at Sheeth Date Considered 8/18/04

<sup>\*</sup>EXAMINER: Initial inference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.